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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,294	07/06/2001	Carol T. Schembri	10990631-2	7409

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AGILENT TECHNOLOGIES, INC.
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EXAMINER
SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 09/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/900,294	SCHEMBRI ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *51-59,63-67 and 69-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51-59,63-67 and 69-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Specification

1. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

3. The disclosure is objected to because of the following informalities: The disclosure makes reference to US Patent applications, however, the current status of the applications is not indicated.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 51-59,63-67 and *69-71* rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

claimed invention. Attention is directed to the decision of *Vas-Cath Inc. v. Mahurkar* 19 USPQ2d 1111 (CAFC, 1991):

> This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 USC 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the "applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*

6. For convenience, claim 51, the only independent claim, is reproduced below.

51. (AMENDED) A method for conducting a hybridization assay within an enclosed hybridization chamber, comprising:

(a) providing a device comprised of a (i) a substrate having a surface with at least a portion of said surface representing a hybridization region, wherein a plurality of oligonucleotide probes are bound to the substrate surface within the hybridization region and arranged in a spatially defined and physically addressable manner, and (ii) a cover which sealingly contacts the substrate surface about the hybridization region, wherein the cover and the hybridization region form an enclosure having an interior space comprising a hybridization chamber; and

(b) introducing into the hybridization chamber a sample fluid comprising (i) a target molecule which may hybridize to a surface-bound molecular probe within the hybridization region, (ii) a hybridization buffer, and (iii) a surfactant of a type and present at a concentration effective to substantially reduce nonspecific binding and promote mixing of components within the sample fluid; and

(c) maintaining hybridization conditions within the hybridization chamber for a period of time sufficient to allow hybridization between the target molecule and a surface-bound molecular probe to occur;

wherein the surfactant is a polymeric nonionic surfactant which is polyethylene oxide.

7. The claimed method has been interpreted as encompassing the use of virtually any concentration of polymeric nonionic surfactant (polyethylene oxide) and where the hybridization chamber of the "device" has virtually and volume and is of virtually any dimension. A review of the disclosure, however, fails to find an adequate written description that would support such breadth of scope. In support of this position, attention is directed to page 15, which states:

> The surfactant generally represents between about 0.1 wt. % and 10 wt.% of the sample fluid, preferably between about 0.5 wt.% and 5 wt.% of the sample fluid, more preferably between about 0.75 wt.% and 5 wt.% of the sample fluid; however, it should be emphasized that the exact concentration will vary with the surfactant selected, and those skilled in the art may readily optimize the concentration with respect to the desired results, i.e., reduction of nonspecific binding and facilitation of mixing within the sample fluid. An exemplary sample fluid will contain between about 0.1 wt.% and about 1 wt.% of polyethylene oxide and between about 0.05 wt.% and about 1 wt.% lithium lauryl sulfate. (Emphasis added)

As can be seen above, at the broadest, applicant contemplated a range of from "about 0.1 wt. % and 10 wt.% of the sample fluid" where any nonionic surfactant was to be used, and then contemplated a range of from "0.1 wt.% and about 1 wt.%" when polyethylene oxide was being used. Such disclosure does not provide adequate support for a range that is without limits, as is the present case.

8. Attention is also directed to page 13, last paragraph, bridging to page 14, of the specification, herein dimensions of the device are disclosed.

> This chamber height may range from about 0.002" to 0.02" (50 μm to 500 μm). The dimension of the cover, the peripheral lip, and the reaction area are such that the reaction area is generally in the range of about 4 mm^2 to 500 mm^2, preferably about 20 mm^2 to 350 mm^2, and the reaction chamber has a volume in the range of about 0.2 μl to about 312 μl, preferably about 1 μl to 200 μl.

As seen above, the specification does not provide an adequate description of the device to be sued in the claimed method whereby said device has virtually any surface area or chamber

volume. While applicant may argue that alternative device dimensions and alternative concentrations of surfactant would have been obvious to those of skill in the art, obviousness cannot be relied upon in satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

> Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

9. Accordingly, and in the absence of convincing evidence to the contrary, the claims are not adequately supported by the original disclosure such that the disclosure reasonably suggests that applicant was in possession of he claimed invention at the time of filing. Applicant is urged to consider narrowing the scope of the claims to those embodiments adequately described in the original disclosure.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

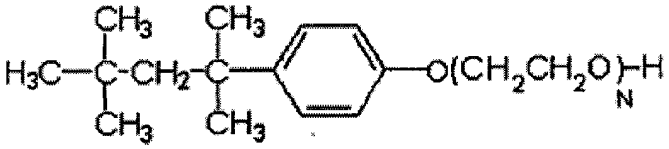
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 51-59, 63-65, 66-67, and 69-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schnipelsky et al., or Zander et al. in view of Wilding et al., and Livak et al.

14. For purposes of examination, the term "polyethylene oxide" has been interpreted as encompassing any of the TRITON X surfactants. Support for this interpretation is based upon pages 13-14 of the disclosure, reproduced below.

preferred. A preferred polymeric nonionic surfactant is polyethylene oxide, with particularly preferred polyethylene oxides comprising an alkylphenol ethylene oxide condensate. Such surfactants may be obtained commercially under the trade name "Triton" from the Sigma Chemical Company (St. Louis, MO), and including, for example, Triton X-100 (octylphenol ethylene oxide condensate) and Triton X-102 (also an octylphenol ethylene oxide condensate). More specifically, Triton X surfactants have been described as having the formula:



(I)

in which N for Triton X-100 has an average of about 9.5 units per molecule while for Triton X-102 N is an average of about 12.5 units per molecule. Further information on both Triton X-100 and Triton X-102 can be found at the following Internet addresses: "www.sigma-aldrich.com/sigma/proddata/t6878.htm" and "www.sigma-aldrich.com/sigma/proddata/t6878x.htm".

15. Schnipelsky et al., disclose a device for use in conducting a nucleic acid amplification reaction and hybridizing the amplicons to immobilized probes. As seen in Figure 1, element **40** is directed to a hybridization chamber where probes are immobilized.

16. Schnipelsky et al., do not specifically disclose the volumes of the hybridization reaction or the use of a surfactant.

17. Zander et al., also disclose a device for conducting amplification reactions as well as hybridization reactions where a probe is bound to the surface of the device and is located within a hybridization chamber.

18. Like Schnipelsky et al., Zander et al., does not define the reaction volumes or the use of a surfactant.

19. Wilding et al., disclose a device that is characterized as being "mesoscale." Dimensions of the fluid communicating means and chambers are found at columns 7-8. Such disclosures are considered to render obvious the presently claimed reaction volumes. Column 13 teaches specifically of having capture reagents bound to the support and that they may be located within a chamber.

20. The use of a surfactant in the hybridization reaction is not specifically disclosed.

21. Livak et al., column 16, penultimate paragraph, disclose using a hybridization buffer that comprises "Triton X-100."

22. It would have been obvious to one of ordinary skill in the art at the time that the invention was made to have modified the devices and associated method of either Schnipelsky et al., or Zander et al., with that of Wilding et al., and Livak et al., whereby one of ordinary skill in the art would be able to effect hybridization reactions within a hybridization chamber that allows for but a very limited amount of hybridization buffer and wherein the hybridization buffer comprises a polyethylene oxide surfactant (Triton X-100). In view of the well-developed state of the prior art, and the detailed guidance provided, the ordinary artisan would have been both motivated and would have had a most reasonably expectation of success.

23. For the above reasons, and in the absence of convincing evidence to the contrary, the invention of claims 51-59, 63-65, 66-67, and 69-71 is rendered obvious by the prior art of record.

Conclusion

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

25. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

26. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

B. L. Sisson

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS